

1 **TITLE 22 EXAMINING BOARDS**  
2 **PART 15 TEXAS STATE BOARD OF PHARMACY**  
3 **CHAPTER 291 PHARMACIES**  
4 **SUBCHAPTER B COMMUNITY PHARMACY (CLASS A)**

5  
6 **§291.33 Operational Standards**  
7

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9 XXX

10  
11 (i) Automated devices and systems.

12  
13 (1) Automated compounding or counting devices. If a pharmacy uses automated compounding  
14 or counting devices:

15  
16 (A) the pharmacy shall have a method to calibrate and verify the accuracy of the automated  
17 compounding or counting device and document the calibration and verification on a routine  
18 basis;

19  
20 (B) the devices may be loaded with bulk or unlabeled drugs only by a pharmacist or by  
21 pharmacy technicians or pharmacy technician trainees under the direction and direct  
22 supervision of a pharmacist;

23  
24 (C) the label of an automated compounding or counting device container shall indicate the  
25 brand name and strength of the drug; or if no brand name, then the generic name, strength, and  
26 name of the manufacturer or distributor;

27  
28 (D) records of loading bulk or unlabeled drugs into an automated compounding or counting  
29 device shall be maintained to show:

30  
31 (i) name of the drug, strength, and dosage form;

32  
33 (ii) manufacturer or distributor;

34  
35 (iii) manufacturer's lot number;

36  
37 (iv) manufacturer's expiration date;

38  
39 (v) date of loading;

40  
41 (vi) name, initials, or electronic signature of the person loading the automated compounding  
42 or counting device; and

43  
44 (vii) signature or electronic signature of the responsible pharmacist; and

45  
46 (E) the automated compounding or counting device shall not be used until a pharmacist  
47 verifies that the system is properly loaded and affixes his or her signature to the record as  
48 specified in subparagraph (D) of this paragraph.

49  
50 (2) Automated pharmacy dispensing systems.  
51

52 (A) Authority to use automated pharmacy dispensing systems. A pharmacy may use an  
53 automated pharmacy dispensing system to fill prescription drug orders provided that:

54  
55 (i) the pharmacist-in-charge is responsible for the supervision of the operation of the system;

56  
57 (ii) the automated pharmacy dispensing system has been tested by the pharmacy and found  
58 to dispense accurately. The pharmacy shall make the results of such testing available to the  
59 board upon request; and

60  
61 (iii) the pharmacy will make the automated pharmacy dispensing system available for  
62 inspection by the board for the purpose of validating the accuracy of the system.

63  
64 (B) Quality assurance program. A pharmacy which uses an automated pharmacy dispensing  
65 system to fill prescription drug orders shall operate according to a written program for quality  
66 assurance of the automated pharmacy dispensing system which:

67  
68 (i) requires continuous monitoring of the automated pharmacy dispensing system; and

69  
70 (ii) establishes mechanisms and procedures to test the accuracy of the automated  
71 pharmacy dispensing system at least every six months and whenever any upgrade or change is  
72 made to the system and documents each such activity.

73  
74 (C) Policies and procedures of operation.

75  
76 (i) When an automated pharmacy dispensing system is used to fill prescription drug orders,  
77 it shall be operated according to written policies and procedures of operation. The policies and  
78 procedures of operation shall:

79  
80 (I) provide for a pharmacist's review, approval, and accountability for the transmission of  
81 each original or new prescription drug order to the automated pharmacy dispensing system  
82 before the transmission is made;

83  
84 (II) provide for access to the automated pharmacy dispensing system for stocking and  
85 retrieval of medications which is limited to licensed healthcare professionals or pharmacy  
86 technicians acting under the supervision of a pharmacist;

87  
88 (III) require prior to use, that a pharmacist checks, verifies, and documents that the  
89 automated pharmacy dispensing system has been accurately filled each time the system is  
90 stocked;

91  
92 (IV) provide for an accountability record to be maintained which documents all transactions  
93 relative to stocking and removing medications from the automated pharmacy dispensing  
94 system;

95  
96 (V) require a prospective drug regimen review is conducted as specified in subsection  
97 (c)(2) of this section; and

98  
99 (VI) establish and make provisions for documentation of a preventative maintenance  
100 program for the automated pharmacy dispensing system.

101

102 (ii) A pharmacy which uses an automated pharmacy dispensing system to fill prescription  
103 drug orders shall, at least annually, review its written policies and procedures, revise them if  
104 necessary, and document the review.

105  
106 (D) Recovery Plan. A pharmacy which uses an automated pharmacy dispensing system to fill  
107 prescription drug orders shall maintain a written plan for recovery from a disaster or any other  
108 situation which interrupts the ability of the automated pharmacy dispensing system to provide  
109 services necessary for the operation of the pharmacy. The written plan for recovery shall  
110 include:

111  
112 (i) planning and preparation for maintaining pharmacy services when an automated  
113 pharmacy dispensing system is experiencing downtime;

114  
115 (ii) procedures for response when an automated pharmacy dispensing system is  
116 experiencing downtime; and

117  
118 (iii) procedures for the maintenance and testing of the written plan for recovery.

119  
120 (E) Final check of prescriptions dispensed using an automated pharmacy dispensing system.  
121 For the purpose of §291.32(c)(2)(D) of this title (relating to Personnel), a pharmacist must  
122 perform the final check of all prescriptions prior to delivery to the patient to ensure that the  
123 prescription is dispensed accurately as prescribed.

124  
125 (i) This final check shall be considered accomplished if:

126  
127 (I) a check of the final product is conducted by a pharmacist after the automated pharmacy  
128 dispensing system has completed the prescription and prior to delivery to the patient; or

129  
130 (II) the following checks are conducted by a pharmacist:

131  
132 (-a-) if the automated pharmacy dispensing system contains bulk stock drugs, a  
133 pharmacist verifies that those drugs have been accurately stocked as specified in subparagraph  
134 (C)(i)(III) of this paragraph; and

135  
136 (-b-) a pharmacist checks the accuracy of the data entry of each original or new  
137 prescription drug order entered into the automated pharmacy dispensing system.

138  
139 (ii) If the final check is accomplished as specified in clause (i)(II) of this subparagraph, the  
140 following additional requirements must be met.

141  
142 (I) The dispensing process must be fully automated from the time the pharmacist releases  
143 the prescription to the automated pharmacy dispensing system until a completed, labeled  
144 prescription ready for delivery to the patient is produced.

145  
146 (II) The pharmacy has conducted initial testing and has a continuous quality assurance  
147 program which documents that the automated pharmacy dispensing system dispenses  
148 accurately as specified in subparagraphs (A) and (B) of this paragraph.

149  
150 (III) The automated pharmacy dispensing system documents and maintains:

151

152 (-a-) the name(s), initials, or identification code(s) of each pharmacist responsible for the  
153 checks outlined in clause (i)(II) of this subparagraph; and

154  
155 (-b-) the name(s), initials, or identification code(s) and specific activity(ies) of each  
156 pharmacist, pharmacy technician, or pharmacy technician trainee who performs any other  
157 portion of the dispensing process.

158  
159 (IV) The pharmacy establishes mechanisms and procedures to test the accuracy of the  
160 automated pharmacy dispensing system at least every month rather than every six months as  
161 specified in subparagraph (B) of this paragraph.

162  
163 (3) Automated checking device.

164  
165 (A) For the purpose of §291.32(c)(2)(D) of this title, the final check of a dispensed prescription  
166 shall be considered accomplished using an automated checking device provided:

167  
168 (i) a check of the final product is conducted by a pharmacist prior to delivery to the patient or  
169 the following checks are performed by a pharmacist:

170  
171 (I) the prepackaged drug used to fill the order is checked by a pharmacist who verifies that  
172 the drug is labeled and packaged accurately; and

173  
174 (II) a pharmacist checks the accuracy of each original or new prescription drug order.

175  
176 (ii) the prescription is dispensed, labeled, and made ready for delivery to the patient in  
177 compliance with Class A (Community) Pharmacy rules; and

178  
179 (iii) prior to delivery to the patient:

180  
181 (I) the automated checking device confirms that the correct drug and strength has been  
182 labeled with the correct label for the correct patient; and

183  
184 (II) a pharmacist performs all other duties required to ensure that the prescription has been  
185 dispensed safely and accurately as prescribed.

186  
187 (B) If the final check is accomplished as specified in subparagraph (A) of this paragraph, the  
188 following additional requirements must be met.

189  
190 (i) The pharmacy has conducted initial testing of the automated checking device and has a  
191 continuous quality assurance program which documents that the automated checking device  
192 accurately confirms that the correct drug and strength has been labeled with the correct label for  
193 the correct patient.

194  
195 (ii) The pharmacy documents and maintains:

196  
197 (I) the name(s), initials, or identification code(s) of each pharmacist responsible for the  
198 checks outlined in subparagraph (A)(i) of this paragraph; and

199  
200 (II) the name(s) initials, or identification code(s) and specific activity(ies) of each  
201 pharmacist or pharmacy technician who perform any other portion of the dispensing process.  
202

203 (iii) The pharmacy establishes mechanisms and procedures to test the accuracy of the  
204 automated checking device at least monthly.

205  
206 (4) Automated storage and distribution device. A pharmacy may use an automated storage  
207 and distribution device to deliver a previously verified prescription to a patient or patient's agent  
208 when the pharmacy is open or when the pharmacy is closed as specified in subsection  
209 (b)(3)(B)(iii) of this section, provided:

210  
211 (A) the device is used to deliver refills of prescription drug orders and shall not be used to  
212 deliver new prescriptions as defined by §291.31(29) of this title (relating to Definitions);

213  
214 (B) the automated storage and distribution device may not be used to deliver a controlled  
215 substance;

216  
217 (C) drugs stored in the automated storage and distribution device are stored at proper  
218 temperatures;

219  
220 (D) the patient or patient's agent is given the option to use the system;

221  
222 (E) the patient or patient's agent has access to a pharmacist for questions regarding the  
223 prescription at the pharmacy where the automated storage and distribution device is located, by  
224 a telephone available at the pharmacy that connects directly to another pharmacy, or by a  
225 telephone available at the pharmacy and a posted telephone number to reach another  
226 pharmacy;

227  
228 (F) the pharmacist-in-charge is responsible for the supervision of the operation of the system;

229  
230 (G) the automated storage and distribution device has been tested by the pharmacy and  
231 found to dispense prescriptions accurately. The pharmacy shall make the results of such testing  
232 available to the board upon request;

233  
234 (H) the automated storage and distribution device may be loaded with previously verified  
235 prescriptions only by a pharmacist or by pharmacy technicians or pharmacy technician trainees  
236 under the direction and direct supervision of a pharmacist;

237  
238 (I) the pharmacy will make the automated storage and distribution device available for  
239 inspection by the board;

240  
241 (J) the automated storage and distribution device is located within the pharmacy building  
242 whereby pharmacy staff has access to the device from within the prescription department and  
243 patients have access to the device from outside the prescription department. The device may  
244 not be located on an outside wall of the pharmacy and may not be accessible from a drive-thru;

245  
246 (K) the automated storage and distribution device is secure from access and removal of  
247 prescription drug orders by unauthorized individuals;

248  
249 (L) the automated storage and distribution device has adequate security system to prevent  
250 unauthorized access and to maintain patient confidentiality; and  
251

252 (M) the automated storage and distribution device records a digital image of the individual  
253 accessing the device to pick-up a prescription and such record is maintained by the pharmacy  
254 for two years.